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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Application of
CURT I. CIVIN)
Serial No. 055,942) Group Art Unit 128
Filed: June 1, 1987)
For: HUMAN STEM CELLS AND)
MONOCLONAL ANTIBODIES)

) SEP 19 PM 4:45
) GROUP 180

INFORMATION DISCLOSURE STATEMENT

Honorable Commissioner of Patents
and Trademarks
Washington, D.C. 20231

Sir:

The following references, which are divided into several categories, are submitted in the subject application.

The enclosed article "Antigenic Analysis of Hematopoiesis III. A Hematopoietic Progenitor Cell Surface Antigen Defined by a Monoclonal Antibody Raised Against KG-1a Cells," by Civin, C.I. (the inventor here), et al J. Immunology 133:157-165 (1984) discloses the monoclonal antibody which recognizes a human hematopoietic progenitor cell surface antigen. The article was published after the filing of the parent application S.N. 670,740.

In addition, the following two abstracts, of which the inventor is an author, are dated more than a year before the subject filing date. They refer to My10 and the monoclonal antibody which recognizes it, but neither enables one without undue experimentation to make the hybridoma that produces the antibody that uniquely recognizes a unique antigen on a stem cell, or the antibody itself. These abstracts do not provide an impetus that would lead one skilled in the art to an antibody to a human pluripotent lympho-hematopoietic stem cell.

Civin, Strauss et al (1982) Blood 60(5):95a (abstract);

Civin, Vaughan et al "Cell Surface Antigens of Human Myeloid Cells," (1982) Exp. Hematol. 10:129 (abstract).

The following articles, of which the inventor is an author, are dated less than one year before the filing of this application.

Civin, Brovall et al (1983) Hybridoma 2:125a, presented Feb. 8, 1983,
abstracts available Feb. 6, 1983;

Brovall, Shaper, Civin et al (1983) Exp. Hematol. 11 (Supp.):199, presented
July 14, 1983, abstract available July 10, 1983.

Civin, Vaughan et al (1983) Exp. Hematol. 11 (Supp.): 84, presented July
12, 1983, abstract available July 10, 1983;

Strauss & Civin (1983) Exp. Hematol. 11:20 presented July 14, 1983,
abstracts available July 10, 1983;

Strauss, LaRusa and Civin (1984) I.S.E.H. Abstract;

Leary, Ogawa, Civin et al (1984) I.S.E.H. Abstract.

A copy of a Declaration of Dr. Civin is submitted herewith. It was originally filed in the parent application S.N. 670,740. It states that Dr. Civin, the applicant, was the sole inventor of the subject matter described in the application.

The following two references teach the use of two antibodies which were speculated to be able to recognize stem cells, RFB-1 and RFB-HLA-DR. However, the Bodger references as well as subsequent experimentation have shown that each of these antibodies also recognizes mature lymphoid and myeloid cells. A copy of a Rule 132 Declaration of the inventor, originally submitted in the parent application S.N. 670,740, is submitted herewith which states that the RFB-1 antibody reacts with many types of mature lymphoid and myeloid cells.

Bodger et al, "Surface Antigenic Determinants on Human Pluripotent and Unipotent Hematopoietic Progenitor Cells", Blood, Vol. 61, pp. 1006-1010 (1983).

Bodger et al, "A Monoclonal Antibody Specific for Immature Hematopoietic Cells and T Lineage Cells", J. Immunology, pp. 2269-2274 (1981).

The Civin, J. Immunology article cites as references the following papers (which we attach for the record) and explains their possible relevance. These have been reviewed and are deemed less relevant than the art cited above.

Nadler et al (1981) Prog. Hematol. 12:187-225;

Reinherz et al (1980) N. Engl. J. Med. 303:370;

Ritz et al (1980) Nature 283:583;

Stashenko et al (1980) J. Immunol. 125:1678.

Monoclonal antibodies which recognize mature T-cells were, of course, also known. Patents which disclose such monoclonal antibodies include:

Reinherz, U.S. Patent 4,443,427;

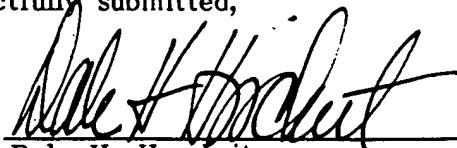
Kung et al, U.S. Patent 4,381,295; and

Bieber et al, U.S. Patent 4,381,292.

Winchester et al (1977) Proc. Nat'l. Acad. Sci. USA, 74: 4012, describes a polyvalent antibody to antigens on B lymphocytes.

Respectfully submitted,

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